IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION, and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, *Boehringer*, v. MYLAN PHARMACEUTICALS INC., MYLAN INC., and MYLAN LABORATORIES LIMITED, *Defendants*.	C.A. No. 20-cv-19 (TSK) Lead C.A. No. 20-cv-90 (TSK) Consolidated

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR CONTINUANCE REGARDING EXPERT DISCOVERY AND TRIAL AND MOTION FOR EXPEDITED BRIEFING SCHEDULE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Rules

I. INTRODUCTION

Boehringer's Motion has a singular purpose: delay trial for as long as possible. But a decision in this case by or around the expiration of all regulatory exclusivities is important. Thus, there is a clear interest in keeping with a schedule that allows the Court ample time to try the case and issue a decision. The current schedule allows for exactly that—and further avoids the burden of injunctive papers.

Boehringer knows all this. But it has nonetheless engaged in filing serial motions to manufacture discovery issues in the hopes that this Court will simply push out discovery and, therefore, postpone the trial. This tactic should not be countenanced. Mylan wants this case efficiently resolved on the merits. Mylan's ANDAs have tentative approval from the FDA and are eligible for final approval as early as November of 2025,[1] and therefore a favorable decision may permit Mylan to offer a generic version of Boehringer's branded pharmaceuticals at that time. For that reason, Mylan has consistently opposed any extension of the trial date that would delay resolution of these important issues in a timely fashion. Boehringer's present Motion for Continuance is another meritless attempt to introduce precisely such a delay—this time, by mischaracterizing *standard, appropriate rebuttal expert opinions* as "new arguments" or "new theories."

Much of this Motion reproduces arguments presented in Boehringer's previous Motion to Strike, using it as an improper vehicle for additional briefing on a fully submitted motion. Expert discovery has now borne out Mylan's previous position that there was no prejudice and striking is

---

[1] The November of 2025 timeframe is important in this case. Boehringer has a patent covering linagliptin that expires (with an added period of pediatric exclusivity) on November 2, 2025. Mylan has not challenged that patent, and is therefore not seeking final FDA approval until that time. If Mylan obtains such approval, a launch without the benefit of a decision on the merits in this case may result in requests for injunctive relief.

an extreme and unwarranted remedy. Now, the ostensible "transgressions" (Mot. 1) Boehringer brings before the Court—on an emergency expedited basis, no less—are nothing more than expert opinions presented in rebuttal and reply reports on issues where Plaintiffs bear the burden of proof. As with its Motion to Strike, Boehringer's Motion for Continuance tries to create the impression that Mylan is a bad-faith litigant by characterizing ordinary conduct as gamesmanship. But amid its overheated and misleading references to "transgressions" (Mot. 2) and supposed "trial by ambush" (Mot. 8), Boehringer conspicuously fails to identify any authority to suggest that it is improper for experts to directly *respond* to opinions in expert reports that are, by their nature, *responsive*. *See, e.g.*, Fed. R. Civ. P. 26(a)(2)(D)(ii). Indeed, that is the whole point.

Proceeding from its mischaracterizations, Boehringer asserts that the standard process of expert rebuttal has "deprived Boehringer of any chance to obtain discovery and respond to these theories." Mot. 2. But that is false. Mylan's experts have set forth their *opinions* based on their expertise and interpretation of documents. For example, Boehringer contends that Dr. Banakar's opinion pointing out what Mylan's ANDA expressly states in response to Boehringer's infringement theory requires additional discovery into Mylan's manufacturing processes. But Mylan and Boehringer have (and have had for many years) equal access to the documents at issue. What is in dispute is Dr. Banakar's expert opinion and analysis of that document—no further factual development is necessary. The opportunity to "obtain discovery and respond" to an expert's rebuttal opinions is to *depose* the expert; *cross-examine* the expert; and offer evidence and argument to *undermine or contradict* those opinions. What Boehringer is *not* entitled to do is halt the case for six months to conduct additional fact discovery—particularly when it remains unable to plausibly identify any such discovery it would genuinely need.

Because Mylan's expert reports were appropriate and timely, and because Boehringer's previous Motion to Strike was without merit, there is no reason this case cannot be tried on the existing schedule. Boehringer's Motion should be denied.

II. ARGUMENT

A scheduling order "may be modified only *for good cause* and with the judge's consent." Fed. R. Civ. P. 16(b)(4) (emphasis added); *see* LR Civ. P. 16.01(f)(1). Boehringer appears to contend that the "good cause" here is conduct by Mylan that, according to Boehringer, "has greatly expanded the scope of this case on three occasions in the last eight months." Mot. 8. In turn, it argues, that conduct "deprived Boehringer of a fair chance to take discovery on [the issues] and to prepare responsive positions." *Id.* Boehringer's mischaracterizations of ordinary litigation conduct and standard expert practice fail to establish *any* cause to delay the case—let alone the requisite *good* cause.

A. Boehringer's Fully Briefed Motion to Strike Is Meritless and Irrelevant Here

Boehringer dedicates at least six pages of its Motion to repeating meritless arguments presented in support of their previous Motion to Strike. *See* Mot. 1-2, 4-5, 8-9. For the reasons stated in Mylan's Opposition to that Motion, Mylan's Final Invalidity Contentions were not improper. They complied with the Scheduling Order that Boehringer agreed to. (Dkt. No. 238-1 at 12-14). They did not "revamp[]" or "drastically expand[]" (Mot. 8) Mylan's invalidity case; none of the theories were "new" and the prior art references at issue were either *explicitly* or *substantively* disclosed, or duplicative of or secondary to prior art long known by the parties. (Dkt. No. 238-1 at 16-17, 22-24.) And Boehringer identified *no plausible prejudice* from the updated contentions. (*Id.* at 16-21.)

Most bewildering about Plaintiffs' decision to waste the parties' and the Court's time rehashing its earlier motion is that those arguments are simply irrelevant to this Motion for

Continuance. They have been outpaced by events. Since the meritless Motion to Strike, as Mylan correctly predicted, the parties were able to "fully and adequately address" the prior art references and invalidity theories at issue in expert discovery. (Dkt. No. 238-1 at 3, 6.) Boehringer continues to insist that it *might have been* prejudiced (Mot. 9), but tellingly does not explain how its completely theoretical deprivation of an opportunity for additional fact discovery *actually prejudiced* it where it mattered—namely, when marshaling expert opinions during expert discovery. That is because, as Mylan established, there was no possibility of prejudice in the first place. Boehringer is transparently leaning on its earlier, since-refuted protestations of prejudice to pad out a flimsy demand to delay this case indefinitely.

B. Non-Infringement Opinions of Mylan's Expert Are Appropriate Rebuttal Opinions—Not "New Theories" Subject to Detailed Advance Disclosure

Boehringer's first argument for a continuance is that Dr. Umesh Banakar's Rebuttal Expert Report includes "three new non-infringement arguments" or "theories," and that his rebuttal expert opinions are improper and prejudicial. Mot. 10. They are neither.

Plaintiffs bear the burden of proving infringement. And it is axiomatic that "all details of a non-infringement defense need not be disclosed in non-infringement contentions." *TQ Delta, LLC v. ADTRAN, Inc.*, No. CV 14-954-RGA, 2021 WL 3728919, at *4 (D. Del. Aug. 23, 2021). That is especially true when it comes to expert opinions, which by nature require the thoughtful, elaborate application of expertise to evidence—and even more so when experts *critique* the opinions of other experts. Rebuttal reports "are by nature responsive, and necessitate a showing of facts supporting the opposite conclusion of those at which the opposing party's experts arrived." *Bone Care Int'l, LLC v. Sentech Pharms., Inc.*, No. 08-CV-1083, 2010 WL 3894444, at *15 (N.D. Ill. Sept. 30, 2010). Accordingly, they may "contradict or rebut evidence on the same subject matter identified by the opposing party's expert report," *Cirba Inc. v. VMware, Inc.*, No. CV 19-

742-GBW, 2023 WL 6799267, at *5 (D. Del. Mar. 30, 2023) (cleaned up), and "rebuttal reports may cite new evidence and data so long as the new evidence and data is offered to directly contradict or rebut the opposing party's witness." *Seltzer v. Squires*, No. CV 2:19-1712-RMG, 2020 WL 12771399, at *2 (D.S.C. Dec. 21, 2020) (cleaned up).

The excerpts of Dr. Banakar's Rebuttal Report that Boehringer attaches (Pl. Ex. 4) establish that the opinions in question are not, as Boehringer misleadingly suggests, affirmative arguments or theories. They are *direct rebuttals* of opinions presented in the reports of Boehringer's experts, wholly within the scope of those reports: "Dr. Bristol and Dr. Amiji both opine that meglumine performs substantially the same function in substantially the same way to achieve substantially the same result as arginine. . . . I disagree." Pl. Ex. 4 ¶ 32. That is true of each of the three purported "new arguments" or "theories" Boehringer identifies. *See id.* ¶ 136 ("Dr. Bristol ignores that Mylan's formulation is manufactured in multiple stages and includes a 'linagliptin premix' and 'linagliptin granules' that are initially formulated separately from the metformin hydrochloride."); ¶ 140 ("Drs. Bristol and Amiji . . . ignore BI documents, Mylan documents, and literature that expressly show they act in substantially different ways"); ¶ 148 ("both Drs. Bristol and Amiji fail to address the known and different behavior of meglumine and arginine in the same system, e.g., aldehydes," as shown "[i]n the context of peer reviewed published literature"). According to Boehringer, Dr. Banakar was not allowed to present these rebuttal opinions; by Boehringer's lights, he was apparently only allowed to say "I disagree." That is obviously wrong. He "has the right to explain why he believes [Boehringer's experts] [are] wrong," *Haskins v. First Am. Title Ins. Co.*, No. CIV.A. 10-5044 RMB, 2013 WL 5410531, at *4 (D.N.J. Sept. 26, 2013)—both by *disagreeing* with their opinions and by pointing out *omissions* in the reasoning that render them incorrect.

Each of these three opinions is appropriate expert rebuttal. This should be uncontroversial. Boehringer's experts opened the door to discussing these purported bases of infringement under the doctrine of equivalents. Pointing out that Boehringer's own manufacturing documents refute the opinions of Drs. Bristol and Amiji is nothing more than Dr. Banakar's offering of "data and evidence" in support of his contradictory rebuttal opinion. As to the Fujita reference, Dr. Banakar was clear that it was cited "to explain what is now known about the way meglumine functions," *not* as a prior art reference subject to prior disclosure. Pl. Ex. 4 ¶ 148 n.8. This, too, is not improper. *See, e.g.*, *Intell. Ventures I LLC v. AT&T Mobility LLC*, No. CV 12-193-LPS, 2017 WL 478565, at *5 (D. Del. Jan. 31, 2017) (proper for "report [to] rel[y] on Nazif '529 to rebut the assertions put forth in Dr. Williams's expert report" where "Dr. Shamos does not contend that Nazif '529 is a prior art reference").

Boehringer does not even suggest how Dr. Banakar's use of Boehringer's own documents and the Fujita reference to refute an incorrect opinion are unfairly prejudicial. Rather, it only identifies Dr. Banakar's opinion about Mylan's "manufacturing process" as "acute[ly]" prejudicial because it "is a *factual* contention." Mot. 10. Again, however, this is wrong. It is an *expert opinion* presented in an *expert report.* As Boehringer points out, Dr. Banakar's explanation of how Mylan's ANDA refutes the opinions of Boehringer's experts relies on the ANDA itself. *Id.* at 14. It does not cite previously undisclosed evidence or documents. It consists of Dr. Banakar's interpretation and understanding of the ANDA, which Boehringer believes to be contradicted by the ANDA. Boehringer already had the opportunity to take factual discovery as to the contents of the ANDA. Dr. Banakar's interpretation and understanding of the ANDA are tested by challenging the basis for the opinion and Dr. Banakar's credibility in making it, and by eliciting testimony from Boehringer's own experts to refute it. *See, e.g.*, *Cave Consulting Grp., Inc. v. OptumInsight, Inc.*, No. 15-CV-03424-JCS, 2018 WL 1938555, at *4 (N.D. Cal. Apr. 25, 2018) ("[E]xperts may . . .

testify at their depositions regarding not only the subject matter of their initial reports but also any critiques of their opinions presented in the rebuttal reports."). In effect, Boehringer is implicitly asserting a *right* to file a *reply*—but, as Boehringer pointed out, the Scheduling Order does not permit a reply, and it has not sought one in its Motion. *See* Mot. 12.

C. The Secondary-Considerations Opinions of Mylan's Experts Are Likewise Appropriate Reply Opinions

"[T]he patentee bears the burden of producing evidence to establish the existence of secondary considerations supporting non-obviousness." *Merck Sharp & Dohme LLC v. Mylan Pharms. Inc.*, No. 1:19CV101, 2022 WL 22855168, at *34 (N.D.W. Va. Oct. 26, 2022). Mylan's Invalidity Contentions repeatedly stated that Mylan was not aware of any secondary considerations that would overcome its case for obviousness. *See* Pl. Ex. 5 at 70, 90, 163, 228. Boehringer's position appears to be that Mylan was required to disclose the full details of its *expert rebuttal*—which by its nature requires expert opinion and knowing the substance of what is being rebutted—well in advance. It cites no local rule or applicable authority requiring *detailed rebuttal opinions* to be disclosed in contentions. Such infeasible frontloading is not how litigation works. *Cf. Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 2:15-CV-1455-WCB, 2017 WL 11807449, at *3 (E.D. Tex. Aug. 3, 2017) ("To expect defendants to produce that type of evidence at an early stage of the case would in effect either require the defendants to greatly accelerate their experts' work without the benefit of discovery, or to hamstring the experts in their examination and discussion of all the evidence pertinent to the obviousness issue.").

Mylan's experts did not offer secondary-considerations opinions in their opening reports; Mylan does not bear the burden of proof on that issue, nor is a defendant required to anticipate a

plaintiff's expert opinions.[2] In their rebuttal reports, Drs. Warren and Rosner articulated detailed opinions on how certain secondary considerations supported a finding of validity. In Reply, Mylan's experts offered their opinions on why *Boehringer's experts were wrong*, relying on their professional experience, expertise, previously disclosed prior art references, and the same evidence Boehringer's experts cited. *See, e.g.*, Pl. Ex. 14 ¶ 70 ("I disagree with the conclusions of Drs. Warren and Rosner regarding the existence or satisfaction of any long-felt unmet need for several reasons."); *id.* ¶ 72 ("I do not believe this article amounts to any industry praise that would support the non-obviousness of the claimed invention."); *id.* ¶ 75 ("I disagree with Dr. Rosner's opinion that evidence of copying is shown by Mylan's submission of its ANDA seeking approval of a generic product that is bioequivalent to Tradjenta."); *id.* ¶ 77 ("I disagree with the opinions of Dr. Rosner and Warren that there is any nexus between the alleged secondary considerations of non-obviousness and the claimed inventions."); Pl. Ex. 13 ¶ 32 ("[A]ll of the purported evidence of secondary considerations of nonobviousness presented by Dr. Amiji lacks a connection to any alleged unique or novel aspect of the claimed inventions cited in the Asserted Patents.").

On their face, these are proper replies with rebuttal opinions falling squarely within the scope of Boehringer's expert reports. *See, e.g.*, *Pers. Audio, LLC v. Google LLC*, No. 17-1751-CFC-CJB, 2021 WL 765763, at *4 (D. Del. Feb. 19, 2021) ("It is proper for a reply expert report to contradict or rebut evidence on the same subject matter identified by the opposing party's expert

---

[2] Indeed, Mylan could not have known that Plaintiffs' experts would offer elaborate opinions regarding, among other things, nexus; alleged long-felt need for combination therapy using linagliptin with other drugs; and alleged unexpectedness of renally impaired patients being able to take linagliptin while on background insulin or sulfonylurea medication. These opinions and others were never adequately disclosed by Boehringer during fact discovery (despite, again, Boehringer bearing the burden on secondary considerations), and its experts relied upon voluminous evidence to support alleged secondary considerations that was first introduced during expert discovery. Experts are allowed to provide *rebuttal* opinions on reply for precisely these reasons.

report; in doing so, it may cite to new evidence and data, so long as this is offered to directly contradict or rebut the opposing party's expert." (cleaned up)).

Nonetheless, Boehringer asserts that the standard appearance of secondary-considerations rebuttal opinions in Mylan's reply reports "denied Boehringer any opportunity to take discovery on the factual underpinnings of Mylan's experts' sweeping new opinions on secondary considerations." Mot. 12. But what possible *fact* discovery would be necessary here? Boehringer identifies none—it only says that it "needs to *review* . . . documents." Mot. 15 (emphasis added). Reviewing documents Mylan's experts were entitled to cite *in permissible rebuttal opinions* is hardly a hardship, let alone a basis for reopening fact discovery. Boehringer also claims it "requires time for its experts to address these opinions." *Id.* But the opinions are not complex. They state a difference of opinion with what Boehringer's experts have *already stated* based on evidence *already available* and cited by Boehringer. That is a quintessential battle of the experts, now teed up for depositions and trial. Boehringer's experts are not entitled to extra time to formulate defenses of long-disclosed opinions.

D. Because Mylan's Expert Reports Contain Only Unexceptional Rebuttal Opinions, There Can Be No Basis for a Continuance

Boehringer's failure to establish good cause means its Motion for Continuance must be denied. Other factors bearing on the modification of scheduling orders, however, also weigh against granting its request.

First, Boehringer suggests that "an extension by five to seven months of the schedule" would not disrupt this litigation. Mot. 15. This is incorrect for two reasons. For one, the request comes *in the middle* of expert discovery, scarcely two weeks before it is scheduled to close, with no depositions yet taken. Reply expert reports were served on July 19, and Mylan provided deposition availability for its experts the same day. Boehringer has only belatedly reciprocated,

until recently taking the position that—despite the existing, unmodified case schedule still in place—it will not participate in depositions unless Mylan withdraws the rebuttal opinions at issue. (Boehringer's unilateral delay has already necessitated scheduling depositions beyond the existing deadlines *without* a Court order.) For another, requesting a delay of nearly *half a year* when Boehringer cannot plausibly identify any fact discovery that it actually needs to try this case on the merits would prolong litigation that both the parties and the Court deserve to see resolved.

Second, Boehringer argues that Mylan would suffer no prejudice. Mot. 15. That is incorrect. As noted, Mylan seeks a decision on infringement and validity by November of 2025 (when pediatric exclusivity expires for a linagliptin patent that Mylan did not challenge). The existing schedule maximizes that likelihood. By contrast, delaying the case another six months could hinder Mylan's ability to make available generic alternatives to Boehringer's monopolized medications.

Third, Boehringer asserts that it is acting in good faith. Mot. 16. But this latest motion is the height of gamesmanship. Boehringer advances a paper-thin argument against appropriate rebuttal opinions that fundamentally mischaracterizes standard expert-report practice. It uses the motion as a vehicle to reargue a meritless Motion to Strike. And although accusing Mylan of "transgressions" and "trial by ambush," it remains unable to plausibly identify any prejudice or improper conduct—only Mylan's refinement of arguments and development of expert evidence inherent in the ordinary course of patent litigation.

III. CONCLUSION

Boehringer's Motion for Continuance should be denied.

Respectfully submitted,

Dated: August 8, 2024

/s/ William J. O'Brien
Gordon H. Copland (WV Bar #828)
William J. O'Brien (WV Bar #10549)

Steptoe & Johnson PLLC
400 White Oaks Blvd.
Bridgeport, West Virginia 26330
(304) 933-8162
gordon.copland@steptoe-johnson.com
william.obrien@steptoe-johnson.com

Deepro R. Mukerjee
Lance Soderstrom
KATTEN MUCHIN ROSENMAN LLP
575 Madison Avenue
New York, NY 10022-2585
(212) 940-8800
deepro.mukerjee@katten.com
lance.soderstrom@katten.com

Joseph M. Janusz
KATTEN MUCHIN ROSENMAN LLP
550 S. Tryon Street, Suite 2900
Charlotte, NC 28280
(704) 444-2000
joe.janusz@katten.com
Attorneys for Mylan

CERTIFICATE OF SERVICE

I certify that, on the 8th day of August 2024, I electronically filed the foregoing "Memorandum In Opposition To Plaintiffs' Motion For Continuance Regarding Expert Discovery and Trial and Motion For Expedited Briefing Schedule" with the Clerk of the Court using the CM/ECF system, which will send notice of the same to all counsel of record.

/s/ William J. O'Brien